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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,765	10/31/2001	Donald T. Shannon	VAS-5041CIP1	5826

7590 05/27/2004

Edwards Lifesciences LLC
Law Dept.
One Edwards Way
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/001,765	Applicant(s) SHANNON ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 114-137 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 114-137 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 114-117, 121-129, 133-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al. (5749880) in view of Frantzen (6042606). Banas et al. disclose an expandable device comprising a tubular graft with a stent over the graft and an outer layer of PTFE wound about the stent, col. 20, lines 1-11. Banas also discloses that self-expanding stents can be incorporated in the stent-graft and made from shape memory material, such as Nitinol, col. 12, lines 60-64. Banas additionally discloses that balloon expandable stents can be employed with the graft, col. 13, lines 24-29. It can be construed that ptfе particles are deposited between the base graft and outer layer since aqueous PTFE can be used, which inherently has particles therein, col. 10, lines 1-5. Banas discloses the inner base graft and outer layer are bonded by heating, col. 9, lines 58-67. However, Banas does not disclose a stent having linear connectors with zigzag elements or that the longitudinal length of the stent remains constant with expansion. Frantzen teaches a stent (Fig. 10) with zigzag elements **20** with adjacent turns connected by a linear connector **90**. Frantzen also teaches it is advantageous to form a stent where the length remains constant with expansion, col. 4, lines 12-14, 40-45, col. 9, lines 35-39. Frantzen additionally teaches the design of the stent that prevents foreshortening is made such that the legs have greater strength to prevent fracturing,

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col. 7, lines 30-38. It would have been obvious to one of ordinary skill in the art to use zigzag elements with a linear connector as taught by Frantzen in the graft of Banas et al. such that it provides a non-foreshortening stent for maximum vessel coverage. The advantages of a non-foreshortening stent are well known in the art.

Claims 114-116, 118, 121-128, 130, 133-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al. (5749880) in view of Lau et al. (6066168). Banas is explained supra. However, Banas does not disclose a stent having linear connectors with sinusoidal elements or that the longitudinal length of the stent remains constant with expansion. Lau et al. teaches a stent (Fig. 11) with sinusoidal elements **12** with adjacent turns connected by a linear connector **13**. Lau also teaches that the length remains constant with expansion of the stent, col. 2, lines 44-46. It would have been obvious to one of ordinary skill in the art to use sinusoidal elements with a linear connector as taught by Lau et al. in the graft of Banas et al. such that it provides a non-foreshortening stent for maximum vessel coverage. The advantages of a non-foreshortening stent are well known in the art.

Claims 119, 120, 131, 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al. '880 in view of Frantzen '606 as applied to claims 114, 126 above, and further in view of Myers et al. (5700285). Banas as modified by Frantzen is explained as before. Banas discloses at least one overlapping layer of tape, col. 13, lines 61-65. However, Banas in view of Frantzen fail to disclose the tape has a thickness less than 0.015 inches. Myers discloses a thickness for the tape less than 0.015 inches, col. 8, lines 3,4. It would have been obvious to one of ordinary skill in the

art to use a tape with a thickness less than 0.015 inches as taught by Myers et al. with the stent-graft of Banas as modified by Frantzen such that it has a low profile making insertion in a catheter or sheath easier.

Response to Arguments

Applicant's arguments filed 3/9/04 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, a non-foreshortening stent is advantageous as it provides the same length of coverage in a vessel once it is expanded, that is it does not lose any length once it is radially expanded. Foreshortening is a disadvantage with some stents that lose lengthwise vessel coverage when they are radially expanded. The examiner respectfully disagrees with the Applicants assertion that a graft that is non-foreshortening is also needed with the stent to match the dimensions once the stent is expanded. There are numerous patents to stent-grafts that do not have stents that are the same length with the grafts because the stents extend beyond the length of the graft to provide anchoring ability, see for example US 5643208, US 5669936 and US 5683449 which all teach stent

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means at the ends beyond the graft for anchoring purposes. Thus, the combinations of either Frantzen or Lau with Banas provide an improved stent-graft and it is not necessary to have a non-foreshortening graft. A surgeon starting with a 1-inch stent before expansion, obviously does not want to lose any of the length due to expansion and therefore a stent that does not foreshorten is a design of great enhancement and preference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-

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5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino

TC 3700, AU 3738

A handwritten signature in cursive script that reads "Brian Pellegrino". The signature is written in black ink and is positioned below the typed name and title.